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U.S.

# Johnson & Johnson Settling Cases Tied to Device That Can Spread Uterine Cancer

Deals related to morcellator use likely to cost many millions of dollars; talks ongoing in other pending actions


Johnson & Johnson pulled its morcellator off the market in July 2014 shortly after the Food and Drug Administration warned of elevated cancer risk. *PHOUTO: MEL EVANS/ASSOCIATED PRESS*

By JENNIFER LEVITZ

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Johnson & Johnson is settling a series of legal claims and lawsuits alleging that its now-discontinued hysterectomy device harmed women by spreading an undetected hidden cancer, according to court documents and plaintiff lawyers with knowledge of the settlements.

An estimated 100 cases have either been filed—or readied for lawsuits—against J&J's Ethicon unit related to a device known as the laparoscopic power morcellator, said Paul Pennock, a plaintiff lawyer and co-lead counsel on the steering committee for consolidated litigation under way in a Kansas City, Kan., federal court.

Of the 100 or so claims, J&J has settled nearly 70 over the past few months, he said, and more talks are ongoing.

J&J's total outlay on the claims likely runs into the many millions, though individual settlement sums vary case by case. Some of its settlements so far have ranged from $100,000 to roughly $1 million, according to a person with knowledge of some recently resolved cases.

The New Brunswick, N.J., health-care giant also is in talks to resolve other morcellator claims it faces, according to lawyers with knowledge of those talks.

J&J also faces a handful of separate morcellation cases that are still pending in state courts.

A J&J spokeswoman declined to comment on the settlements. The company suspended sales of its device in April 2014 and withdrew it from the market in July 2014.

"You certainly don't always see a company step up and take responsibility this early on," the plaintiff lawyer Mr. Pennock said. "That's something we think is appropriate."

Power morcellators cut up benign growths called fibroids so doctors can remove the tissue through tiny incisions. Surgeons routinely deployed the devices before April 2014, when the U.S. Food and Drug Administration warned that women undergoing fibroid operations have a 1 in 350 chance of harboring a uterine sarcoma that can't be reliably detected before the procedure.

Morcellators can spray cancerous tissue within the abdomen and pelvis, significantly worsening a woman's chances of long-term survival, the FDA said.

Doctors used power morcellators in tens of thousands of procedures a year, primarily hysterectomies. J&J's Ethicon unit was just one morcellator maker, though it held the lion's share of the market.

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The U.S. Government Accountability Office continues to probe why the device was allowed to be on the market for two decades before the FDA warned it can spread uterine cancer, according to a person familiar with the investigation. In the past the FDA has defended the regulatory process used to approve morcellators and most devices as a good way to balance innovation and safety, and said the agency is bolstering surveillance of devices on the market.

The wrongful-death and product-liability claims against J&J's Ethicon division generally allege that the company knew or should have known the surgical tools disseminated cancer but didn't take adequate action, and that the products were essentially a defective concept given the difficulty of distinguishing a fibroid from a uterine sarcoma.

J&J said in a statement to the Journal last year that Ethicon morcellators "have always included cautions in their instructions for use about the potential spread of malignant (or suspected malignant) tissue."

In a February hearing in the Kansas court, John Winter, a lawyer at Patterson, Belknap, Webb & Tyler, representing J&J, referred to past "confidential settlement discussions with numerous lawyers" and settlement "discussions, dialogue, resolution" according to a court transcript. Mr. Winter, who declined to comment through J&J, didn't say during the hearing how many cases had been resolved.

The amounts J&J paid in its confidential settlements to individual women who claimed they were harmed by the device could vary depending on such factors as a woman's age, medical condition and whether she had children, according to people familiar with many of the resolutions.

The FDA began looking into possible risks of surgery with the device after then-40-year-old anesthesiologist Amy Reed, went public in a Wall Street Journal article detailing her worsened cancer after a hysterectomy using the device. She has sued another morcellator maker, Karl Storz GmbH, in a case pending in a Massachusetts state court, as well as the Boston hospital and doctors involved in her care. The company didn't respond to a request for comment; the hospital, Brigham and Women's Hospital, said it doesn't discuss pending litigation. Responding in court filings, Karl Storz has moved to dismiss the lawsuit, while the hospital and doctors have denied wrongdoing.

Ms. Reed, a mother of six who now lives outside Philadelphia, has had multiple recurrences and continues to fight advanced cancer. Her husband, Hooman Noorchashm, also a doctor, on Friday lamented that settlements would prevent a public airing of all the facts.

"Each one of these cases is an opportunity to create a public record about what went wrong—both ethically and at a regulatory level—so nothing like it happens again," he said.

Houston lawyer Sean Tracey, whose firm Tracey & Fox settled multiple morcellator cases with J&J in December, said in the Kansas court in February that he has "another 40 power morcellator cases against other defendants that I'm working on," according to a court transcript.

Mr. Pennock believes many women never had the chance to seek redress through the courts. They "died because of this device but those they left behind have no idea what happened to them," he said.

According to court filings, the Tracey & Fox litigation was on track, with an eye on a potential trial this year, before the settlements.

Before the firm settled with Ethicon in December, it had received 100,099 documents in discovery from the company—with the final delivery in November—and in September had formally requested the depositions of two former Ethicon medical directors, the firm's lawyers said in a January filing in Kansas federal court.

Lawyers were pushing for the cases to move quickly given that many of the women were ill.

"Our highest priority has always been to ensure that this unique group of clients, many of whom may not live to see Christmas 2016, received recompense sooner rather than later," wrote attorney Rebecca King, of Tracey & Fox in a December court filing.

One case that settled involved Molly Minihan, a Colorado woman who underwent a laparoscopic surgical procedure in April 2013, according to court filings. "During this surgery," according to the lawsuit, "cancerous tissue was cut, shredded and spread throughout her body."

By December 2015, her uterine leiomyosarcoma had recurred twice despite chemotherapy, her lawyer, Ms. King, wrote in a filing, saying she worried administrative delays would hurt her client and "rob her of her day in court."

In a separate case, Mona Eldin, a family doctor in Michigan, confirmed Thursday that her case had settled.

In a previous interview Ms. Eldin, who is in her 40s, said that when she had a laparoscopic hysterectomy with morcellation for presumed fibroids, her doctor never mentioned the possible risks of a hidden cancer. Meanwhile, the pathology of the shredded tissue initially falsely came back benign. Later retesting of the original tissue—after a tumor grew in Ms. Eldin—revealed it had been sarcoma all along, illustrating another danger of morcellation, her husband, Usama Gabr, also a doctor, said in the previous interview: the device destroyed tissue that pathologists are trained to read. "You can imagine how many people just go undiagnosed," he said. "The danger goes beyond" the FDA's 1 in 350 estimate, he said.

"We've got people that are dying," said their lawyer, François M. Blaudeau, whose Birmingham, Ala., firm, the Southern Institute for Medical and Legal Affairs, settled its morcellator cases against Ethicon, according to a February court transcript.

Write to Jennifer Levitz at jennifer.levitz@wsj.com